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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,887	03/31/2001	Sanjay Kumar	059996.1985	7559

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EXAMINER
SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,887	KUMAR ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *9-14 and 18-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-8, 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election of Group 1: claims 1-18, 21-22, 25 and 26, on January 22, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Through phone calls to Dwayne Mason on 3/24/2003(Interview summary included) and newly appointed counsel, Allan Ratner on 4/9/2003(Interview summary included), the original restriction requirement and elected claims were changed. The revised restriction requirement is as follows:

1. Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-4, 6-14, and 15-17 are drawn to polynucleotides, probes, and methods of gene regulation and synthesizing polypeptides, classified in Class 435, subclasses 69.1, 252.3, and 320.1, Class 536, subclass 23.5, 24.31 and 24.33.

II. Claims 19-20 drawn to methods of transformation as classified in for example Class 435, subclass 419.

III. Claim 23 drawn to a method of making antibodies from unique proteins as classified in Class 530, subclass 350.

IV. Claim 24 drawn to a method of probing with an antibody as classified in Class 530, subclass 387.

V. Claims 27-29 are drawn to a method of correlating polynucleotides with dormancy as classified for example in Class 435, subclass 6.

VI. Claims 5, 18, 21, 22, 25, 26 are drawn to methods of gene regulation and methods of using nucleic acid sequences.

a. Inventions I and V, I and II, and I and VI are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of invention I can be used in a materially different process such as for developing a computer readable format.

b. Inventions I and III, and inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the polynucleotides of invention I are not required to practice the methods of inventions III and IV.

c. Inventions II and III, II and IV, II and V, II and VI III and IV, III and V, III and VI, IV and V, and IV and VI are drawn to patentably distinct methods which involve different method steps, include different reagents and have different objectives. Invention II involves method steps of transforming polynucleotides into plants. Invention III involves method steps involving raising antibodies from unique polypeptides. Invention IV involves method steps of probing with antibodies. Invention V involves method steps to correlate a polynucleotide with the process of dormancy. Finally, invention VI involves cloning nucleic acids and regulating

expression. The methods all have different method steps, objectives and reagents. Therefore the methods are distinct over one another.

Restriction Requirement Applicable to All Groups:

Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to a nucleotide sequence, the Applicants must elect a single nucleic acid sequence from SEQ ID NO: 1-4. Furthermore, if applicant elects group I, then applicant must further elect the pair of claims from claims 7-14 that correspond to the elected sequence from SEQ ID NO: 1-4. For an elected group drawn to a polypeptide, the Applicants must elect a single nucleic acid encoding a single polypeptide from SEQ ID NO:1-4. Finally, for an elected Group drawn to an antibody, the Applicants must elect a single nucleic acid sequence encoding a polypeptide used to generate a single antibody (See MPEP 803.04).

> The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an

independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Finally, the election of Group I, claims 1-4, 6-8, and 15-17 with respect to SEQ ID NO:1 made on 4/9/2003 through a phone conversation with Allan Ratner is the current subject of prosecution.

DETAILED ACTION

Claim Objections

A. Claim 1 needs to end in a period, an "A" should be deleted, and "sequences" should be changed to the singular, "sequence"; correction is required.

B. Claim 4 needs to have "which" inserted before "are associated," correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2, 3, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 2 is indefinite over the recitation of "from the tea bush of the same genetic make up" as it is unclear whether the DNA is cloned from the same tea bush having a genetic make up as that recited in claim 1 or from a tea bush having a genetic make up that is the same as that of the tea bush in claim 1.

B. Claim 3 is also indefinite over the recitation of "from the tea bush of the same genetic make up" as it is unclear whether the DNA is cloned from the same tea bush having a genetic make up as that recited in claim 1 or from a tea bush having a genetic make up that is the same as that of the tea bush in claim 1. Applicant should amend the claims to clarify their intended meaning of this phrase.

C. Claim 17 is indefinite over the recitation of "important sequences" because neither the specification nor claims set forth the criteria for determining when a sequence is important versus unimportant.

D. Claim 17 is further indefinite over the recitation of "etc" because a claim should be complete and set forth all of the embodiments claimed, it is presently not clear as to what is intended to be included by "etc". Applicant should amend the claim to completely set forth all embodiments of their invention as claimed.

35 U.S.C. 101/112 Utility Rejections

35 U.S.C. 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-8, and 15-17 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific, substantial or a well established utility.

The claimed nucleic acid is not supported by a specific asserted utility because the disclosed use of the nucleic acid is not specific and is generally applicable to any nucleic acid. The specification states that the nucleic acids may be useful as a hybridization probe to complementary molecules in other plants using probe design methods, cloning methods, and clone selection as is well known in the art. The specification teaches on page 22 that an embodiment of the invention includes using the novel sequences as probes to look for the sequences of nucleotides in other plants, animal, and/or microbial systems and the like. The novel sequence of SEQ ID NO: 1 is taught to be used to clone full-length cDNA, genomic DNA, promoter and regulatory sequences. Furthermore, an embodiment of modulating winter dormancy using the novel genes in the plants after transferring these genes using the techniques such as bialistic mediated transformation. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed.

Further, the claimed nucleic acid is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acids have asserted or identified specific and substantial utilities. The research contemplated by applicants to characterize potential full length genes and furthermore their protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or

activity for the nucleic acid such that another non-asserted utility would be well established for the compounds.

Claims 1-4, 6-8 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

A review of the language of the claim indicates that the claim is drawn to a genus, i.e., any DNA sequence **comprising** SEQ ID NO:1.

The search indicates that that SEQ ID NO: 1 is a novel and unobvious sequence. There is a single species explicitly disclosed(a molecule consisting of SEQ ID NO: 1 that is within the scope of the claimed genus).

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full length genes, splice variants, cDNAs, and genomic DNA that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO:1 is only a 3' end fragment, of any full length gene or cDNA species. When reviewing a claim that encompasses a widely varying genus, the examiner must evaluate any necessary common attributes or features. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus of, e.g., "a DNA sequence comprising SEQ ID NO:1," encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region. A partial cDNA that did not include a disclosure of any open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding

capacity of any cDNA molecule would be disclosed. Further, defining "the" cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single common structural feature shared by members of the claimed genus i.e., a sequence comprising SEQ ID NO:1. Since the claimed genus encompasses genes yet to be discovered, splice variants, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO:1 does not provide an adequate description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO:1, 2) partial structure of DNAs that are capable of being cloned to SEQ ID NO:1, 3) the breadth of the claim as reading on genes yet to be discovered in addition to numerous splice variants and cDNAs, 4) the lack of correlation between the structure and the function of the 3' end fragment and/or gene; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise a DNA sequence comprising SEQ ID NO:1 and therefore the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER

4/16/2003